55099-A-PCT-US/JPW/AJM/ENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Ilya Trakht

Serial No.: 09/664,485 Examiner: Shanon Foley

Filed: September 18, 2000 Art Unit: 1648

For: DEVELOPMENT OF HUMAN MONOCLONAL ANTIBODIES AND USES THEREOF

1185 Avenue of the Americas
New York, New York 10036
November 3, 2003

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

COMMUNICATION IN RESPONSE TO OCTOBER 1, 2003 RESTRICTION REQUIREMENT

This Communication is submitted in response to the October 1, 2003 Office Action issued by the United States Patent and Trademark Office in connection with the above-identified application. A response to the October 1, 2003 Office Action is due November 1, 2003. However, since November 1, 2003 falls on a Saturday, a response filed Monday, November 3, 2003, is to be considered timely. Accordingly, this Communication is being timely filed.

In the Office Action, the Examiner restricted pending claims 79-110 to one of the following allegedly distinct inventions under 35 U.S.C. §121:

I. Claims 79-82, 89, 90-96, 98, 101 and 106-110, drawn to a composition comprising a monoclonal antibody specific for cancer;

II. Claims 79, 80, 83, 84, 90-97, 99 and 106-110, drawn to a composition comprising a monoclonal antibody against an infectious agent;

III. Claims 79, 80, 85, 86, 89, 90-97, 100 and 106-110, drawn to a composition comprising a monoclonal antibody against a toxin;

IV. Claims 79, 80, 87-89, 90-97 and 105-110, drawn to a composition comprising a monoclonal antibody against an autoimmune disease-related antigen;

V. Claims 79, 80, 89, 90-97, 102 and 106-110, drawn to a composition comprising a monoclonal antibody against an enzyme dysfunction-related antigen;

VI. Claims 79, 80, 89, 90-97, 103 and 106-110, drawn to a composition comprising a monoclonal antibody against a hormone dysfunction-related antigen; and

VII. Claims 79, 80, 89, 90-97, 104 and 106-110, drawn to a composition comprising a monoclonal antibody against an immune dysfunction-related antigen.

In response, applicant hereby elects Group I, claims 79-82, 89, 90-96, 98, 101 and 106-110, drawn to a composition comprising a monoclonal antibody specific for cancer, with traverse, for prosecution at this time.

The Examiner also required the election of species with respect to claim groups I-IV. In response to the Examiner's stipulation that if Group I is elected, a single cancer must be elected, applicant further elects breast cancer.

REMARKS

Applicant, however, respectfully requests that the Examiner reconsider and withdraw the restriction requirement. Under 35 U.S.C. §121, restriction may be required if two or more independent and distinct inventions are claimed in one application. Under M.P.E.P. §803, the Examiner must examine the application on the merits, even though it includes claims to distinct inventions, if the search and examination can be made without serious burden.

The inventions of Groups I-VII are not independent. Under M.P.E.P. §802.01, "independent" means there is no disclosed relationship between the subject matter claimed. The inventions of Groups I-VII are all closely related, in that they relate to a composition comprising a monoclonal antibody against a disease condition or agent. Applicant therefore maintains that Groups I-VII are not independent and restriction is not proper.

Applicant further maintains that the Examiner's stipulated requirement to elect a single cancer if Group I is elected is particularly unwarranted. As the subject specification makes clear (see specification, page 51, lines 19-23), a given antibody will interact with cancers of different tissues provided there is an overlapping tumor antigen. Indeed, the specification provides several examples of antibodies that are specific for both breast and prostate cancer (see, e.g., monoclonal antibodies produced by hybridoma 32-B8, page 59, lines 8-13; hybridoma 32-F6, page 59, lines 18-21; hybridoma 39-A7, page 59, lines 23-25; hybridoma 50-1B3, page 59, lines 27-30; hybridoma 13-42, page 59, line 35 to page 60, line 2; hybridoma 13-82, page 60, lines 9-12; hybridoma 22-8D11, page 60, lines 30-32; hybridoma 3-2H6, page 61, lines 16-18; and hybridoma 32-B8, page 59, lines 8-13). Thus, different cancers may be closely related in that they exhibit antigens in common that are recognized by the respective antibodies. Applicant therefore respectfully submits that restriction to a single type of cancer is not proper.

Moreover, under M.P.E.P. §803, the Examiner must examine the application on the merits if examination can be made without serious burden, even if the application would include claims to distinct or independent inventions. That is, there are two criteria for a proper requirement for restriction: (1) the invention must be independent and distinct, and (2) there must be a serious burden on the Examiner if restriction is not required.

Applicant respectfully submits that there would not be a serious burden on the Examiner if restriction were not required, because a search of the prior art relevant to the claims of Groups II-VII would not impose a serious burden once the prior art relevant to Group I has been identified. Therefore, there would be no serious burden on the Examiner to examine Groups I-VII together in the subject application.

Further, within Group I, once the prior art relevant to an antigen expressed by breast cancer has been identified, a search of the prior art relevant to the expression of this antigen by other cancers would not impose a serious burden. Therefore, there would be no serious burden on the Examiner to examine the binding of an antibody to different cancers together in the subject application. Hence, the Examiner must examine these different cancers on the merits.

In view of the foregoing, applicant maintains that restriction is not proper under 35 U.S.C. §121 and respectfully requests that the Examiner reconsider and withdraw the requirement for restriction.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicant's undersigned attorneys invite the Examiner to telephone them at the number provided below.

No fee is deemed necessary in connection with the filing of this Communication. However, if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:
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